



## Keratoplasty evolution has long and storied history

**C**orneal transplantation has a long and evolved history, with many facets of change and great future possibilities,

**Edward J. Holland, MD**, Cincinnati, said. Dr. Holland delivered the Castroviejo Lecture at the “Advances in Keratoplasty: Where we are in 2013” symposium at the American Academy of Ophthalmology annual meeting.

The evolution of corneal transplantation began with an unsuccessful first attempt in 1838, followed by the discussion of the lamellar keratoplasty approach to corneal disease starting in the late 1800s.

The first successful penetrating keratoplasty (PK) using human tissue was performed in 1906, Dr. Holland said. “Finally, Ramon Castroviejo, of which this medal and lecture is named after, became the preeminent figure in the modern era of corneal transplantation,” Dr. Holland said. “He was very innovative with his surgical techniques ... he was a high volume surgeon and made great contributions to our field.”

PK remained the dominant procedure for decades. “I think back to all the American Academy of Ophthalmology meetings that I went to for years, and we talked about one procedure really—it was just PK,” Dr. Holland said. “And I think we all, as surgeons, got very comfortable with that.” Reasons existed for PK’s continued dominance—one was excellent outcomes, which Dr. Holland said was actually not the case.

“We all, I think, fooled ourselves in saying we had great outcomes because we were defining outcomes as graft clarity. We weren’t talking about quality of vision,” Dr. Holland explained.

However, when compared to outcomes of other subspecialties, such as refractive or cataract surgery, corneal results were not as good, he said. These cases had high astigmatism, with many large studies of PK finding that the average astigmatism was more than 4 D. “We didn’t even try to measure irregular astigmatism,” he said. “It was off the charts.”

There were other issues, including significant intraoperative complications. Dr. Holland said that while many surgeons thought they were doing a good job in the field, “in retrospect, we really weren’t.”

The last decade has seen a rapidly altering corneal surgery paradigm. There was a need for more anatomic targeted procedures, and those procedures sought to avoid the removal of healthy corneal tissue. Endothelial keratoplasty—DSEK or DMEK—was created to treat endothelial disease, while deep anterior lamellar keratoplasty (DALK) was developed to target stromal disease. In more challenging cases, an ocular surface transplant procedure was useful in those instances when PK was not effective. “It’s been a pretty rapid change in our approach to patients with endothelial disease,” Dr. Holland said.

The statistical report from the Eye Bank Association of America, which tracks corneal transplants in the U.S., found that last year, endothelial keratoplasty for the first time “became the most common corneal transplant procedure, overtaking PK, and this is going to continue to rise,” according to Dr. Holland.



**Edward J. Holland, MD**, the 2013 Castroviejo awardee, gives a talk on the history of keratoplasty at the Society-sponsored symposium during the American Academy of Ophthalmology meeting in New Orleans.

“Endothelial keratoplasty has been one of the most significant advances in corneal surgery,” he said. “It’s now the leading indication for keratoplasty, with about 40 to 50% of the patients that we operate on.”

**Gerrit Melles, MD**, Rotterdam, the Netherlands, had the “breakthrough” paper in *Cornea* in 2004 that first described DSEK, and that research had a major impact in the field that reverberates today, Dr. Holland said.

“[DSEK] became the procedure that corneal surgeons across the world embraced and really changed the way we manage our patients with endothelial disease,” Dr. Holland said.

The procedure is still undergoing evolution, with new insertion devices, thin DSEK techniques, and the transition underway to DMEK. The future looks bright, he said. Possibilities include culture endothelial cells and a biosynthetic cornea.

“Where are we going with corneal transplantation? We’ve had quite a bit of change in the last decade and some exciting things going on. I think we’re moving to the cellular level,” Dr. Holland said. **CN**



# Cornea Society

*Advancing the treatment of corneal disease*

Winter 2014

## President's Message

Dear Colleagues,

This message marks the conclusion of my two-year tenure as president of our Society. It has gone by remarkably quickly, and it has indeed been my privilege to serve the Society. In these two years, the Cornea Society has served as an international platform for our field, with the organization of numerous sessions and symposia, both in the U.S. and abroad, and we have established strong ties with the other supranational cornea societies such as the Asia Cornea Society, EuCornea and most recently, the newly inaugurated PanCornea.

My concurrent presidency of the Asia Cornea Society has enabled a very close and vibrant relationship between these two societies spanning two continents, spawning several joint initiatives. An example of this is our joint organization of the first and overwhelmingly successful Cornea Day held outside the U.S. in Singapore in July 2013, alongside the 26th Annual Meeting of the Asia-Pacific Association of Cataract and Refractive Surgeons (APACRS). I am pleased to inform our members that both societies and the APACRS Council are keen to co-organize similar Cornea Days at other APACRS meetings in Asia in the near future. I can see the future of the Society to serve as the international forum for the pursuit of corneal development, and it has been my privilege to do my part in this endeavor.

Also jointly conceptualized and developed by the two societies, CorneaEd was recently launched as an educational initiative devised to provide the corneal community with a database of existing corneal fellowship, observership and training programs in the U.S. and in Asia, with a view to expand such programs to other continents. ACS has already sponsored its first International Corneal Training Grant recipient this year, a young corneal surgeon from Hong Kong. Our Society has received similar applications from young corneal specialists in the U.S., and will shortly be presenting the next International CorneaEd Corneal Training Grant to a deserving member.

Our field is advancing in leaps and bounds epitomized by the breakneck transition in corneal transplantation techniques, from penetrating keratoplasty, to the newest forms of endothelial keratoplasty and deep anterior lamellar keratoplasty, and each symposium organized by the Society brings new knowledge and surgical techniques to the forefront. Descemet's stripping automated endothelial keratoplasty (DSAEK) is now the new gold standard in the surgical treatment of endothelial dysfunction in the U.S., due to its compelling clinical advantages, and Descemet's membrane endothelial keratoplasty (DMEK), in its emerging forms, is perhaps beginning to contest its superiority; however, in many other countries and continents around the world the adoption of EK procedures remains more challenging due to a lack of training opportunities and EK donor access considerations, and the Society can and should continue to play a major role in this regard. Perhaps the converse situation exists in the treatment of corneal stromal disorders—deep anterior lamellar keratoplasty (DALK) is becoming a mainstream procedure for keratoconus and other forms of corneal stromal disease at an international level, but adoption of DALK surgery has been slower in the U.S., and U.S. surgeons could possibly turn to our international colleagues in this instance. The vibrant scientific exchange at international levels between the supranational corneal societies will continue to enhance our efforts to provide better surgical solutions for our corneal patients.

In these last two years, we have seen a tremendous transformation of our *Cornea* journal, under the superb leadership of **Alan Sugar, MD**, editor-in-chief, and his diligent and devoted team who have working tirelessly in totally eliminating the historical backlog of articles, more than halving our submission to print times, developing an electronic Open Access (OA) option, and enhancing *Cornea's* impact factor up to 1.746, ranking it 24th of 58 ophthalmic journals. Thank you, Alan!

Additionally, I want to thank each and every member of our Board of Directors, who have consistently provided me with much-needed support and encouragement (and at unearthly international hours). I must also express my heartfelt appreciation to Gail Reggio, executive director of the Cornea Society, who works tirelessly for the Society to support all the endeavors of the Board and our members, and who has been consistently at my side for the last two years, making sure that all goes well.

A special thanks to **Penny Asbell, MD**, **Gullapali N. Rao, MD**, as well as **David Glasser, MD**, who rotated off the Board on December 31, 2013. David's continued contribution to the Cornea Society Board as immediate past president during my tenure provided invaluable guidance, encouragement, and he was always the voice of reason. David, we will miss you! While this news of our colleagues rotating off the Board is tinged with regret, it is with great pleasure that we welcome our new Board members for 2014, **Francis J. Price, MD**, and **Choun-Ki Joo, MD**, who I am confident will bring fresh ideas and dynamism to the Society. At the same time, we are grateful to continue to have **Michael W. Belin, MD**, and **Terry Kim, MD**, serving one last term as vice president of international relations and vice president of industry relations, respectively. Both Michael and Terry have been invaluable in providing pivotal leadership in these important areas; they also provide a much needed continuity for the Board, as they look toward grooming the next generation of leaders in these posts.

Last, and definitely not least, I would like to announce two new appointments on the Executive Committee: **Marian Macsai, MD**, president-elect, and **Elmer Tu, MD**, secretary/treasurer, effective January 1, 2014. Both Marian and Elmer have made tremendous contributions to the Board and will be stepping up to ensure that our Society remains ambitious, audacious, and astounding in its future achievements.

Finally, and with my heartiest congratulations, I pass the baton to **Christopher J. Rapauno, MD**, who will be our new president of the Cornea Society. With Chris's steadfast leadership, I am fully convinced he will raise the bar, and our Society will continue to evolve to an even higher level. It has been my true privilege and honor to serve as president over these last two years, and I will continue to do my best to serve as your past president for the next two. **CN**

Yours sincerely,  
Donald TH Tan, FRCS



## Incoming President's letter

**A**s I begin my two-year term as president of the Cornea Society, I am quite cognizant of the fact I have big shoes to fill. **Donald Tan, FRCS**, did a remarkable job over the last two years as president, and he was president of the Asia Cornea Society at the same time! I learned a lot from him and will surely turn to him for his guidance over the next two years in his term as past president. I thank him for his leadership and service.

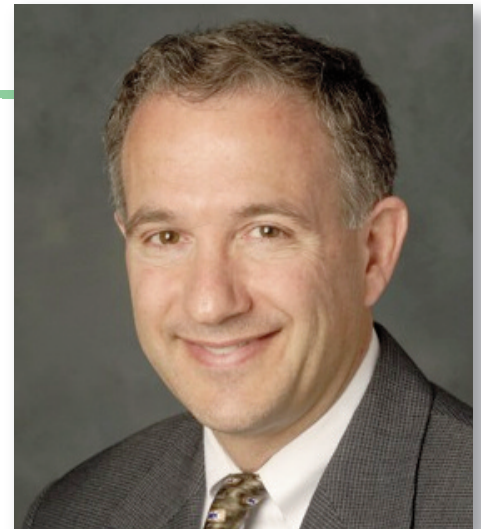
Over the past decade, the Cornea Society has grown tremendously both in the number of our members and in our scope of activities. These accomplishments are due to the hard work of many past presidents and members of the Board of Directors, our executive director, Gail Reggio, and our close working relationship with ASCRS, thanks to David Karcher among others. Over the past 10 years our membership has increased from 252 members to 781 members. During that time we also increased our number on the Board of Directors to 17, which includes at least three international members. As a reminder, to be on the Board of Directors, you need to be a “member with thesis,” which includes a requirement to be first author on a paper based on research performed after your cornea fellowship. I would like to personally welcome our two newest Board members, **Francis Price, MD**, from the U.S., and **Choun-KI Joo, MD**, from Korea.

The Society continues to run Cornea Subspecialty Day at the AAO annual meeting and co-sponsors Cornea Day at the ASCRS•ASOA Symposium & Congress with the

Cornea Clinical Committee. These two programs have been extremely well received and are a highlight of these meetings for many cornea specialists. We also sponsor symposia at the AAO and ASCRS•ASOA annual meetings. And of course, we co-sponsor the Fall Educational Symposium the Friday before the AAO annual meeting with the EBAA. We routinely sponsor a resident or fellow interested in cornea to come to the AAO Mid-Year Forum, with the goal of becoming a better advocate for the cornea subspecialty. Each year we sponsor a breakfast for the cornea fellowship directors, just to get together and discuss topics of shared interest in a relaxed setting. The Society also sponsors the DJ party at the start of the AAO and ASCRS•ASOA meetings each year. We thank **Terry Kim, MD**, and **Tony Aldave, MD**, for their tireless efforts DJ'ing the event.

The Cornea Society runs the *Cornea* journal, whose editor-in-chief is **Alan Sugar, MD**. Over the past two years, Alan and his assistant and associate editors have done a tremendous job eliminating the backlog of publishing accepted papers and cutting the submission to print time in half. The journal's impact factor is rising and it is currently ranked 24th of 58 ophthalmic journals. As the impact factor is based on papers published several years prior, we expect it to continue to rise.

In the fall of 2013, the Society obtained an unrestricted grant from Alcon and ran the Cornea Fellows Educational Summit for the first time. Fifty cornea fellows from around the country met in Fort Worth, Texas for a two-day meeting, which included didactics on a variety of cornea and



**Christopher J. Rapuano, MD**

anterior segment topics and wet labs on DSEK and LASIK. The fellows who participated felt it was a wonderful experience. They especially enjoyed one-on-one interaction with the faculty. With the help of Laura Johnson and Erin Ashe we are submitting another grant and hope to do it again next year. We want to thank the fellowship directors for allowing their fellows to participate.

Another first this past year was co-sponsoring Cornea Day just prior to the Asia-Pacific Association of Cataract and Refractive Surgeons (APACRS) in Singapore with the Asia Cornea Society. The two societies also co-sponsored a symposium at the main meeting. Cornea Day was hugely successful—in fact, the APACRS wants the two societies to do the same thing in two years.

The big project for the Society over the next 18 months is organizing World Cornea Congress VII just prior to the ASCRS meeting in San Diego in April 2015. Learn more about that event in the next newsletter. **CN**

Sincerely,  
Christopher J. Rapuano, MD  
President-Elect



# Cornea symposium brings wealth of knowledge

**T**he Cornea Society held its Fall Educational Symposium on Friday, Nov. 15, 2013. Among the highlights was the Cornea Donor Study 10-year results.

## Donor age makes no difference in graft survival rates

Calling the Cornea Donor Study (CDS) “the most significant study in the history of our specialty,” **Mark Mannis, MD**, Sacramento, Calif., said its 10-year results reiterated findings from the five-year outcomes—donor age is not a factor in graft survival in the majority of cases after penetrating keratoplasty for endothelial disorders. “In the first five years older donor tissue fared better, and there’s a trend in the second five years that younger tissue fares better, but it’s not statistically significant,” he said. At the 10-year point, there was a 21% graft failure rate (of 1,090 enrolled participants), 41% with clear grafts, 19% who died, and 18% with less than 10 years of follow-up. Grafts with a donor age of 66 years or older had a 69% success rate at 10 years, compared with a 74% success rate in donor tissue under 66 years old. “Donor tissue from 34–71-year-olds has a 75% success rate,” he said. “The very old tissue and the very young tissue had diverse outcomes,” with the younger tissue performing much better than the very old tissue. “Successful grafts are more likely with Fuchs’ and no preoperative glaucoma,” said **Ed Holland, MD**, Cincinnati. Additionally, while there was significant cell loss (around 76%) in all groups, “this seems to level off after five years.” Grafts with endothelial cell counts of 1500 or more had a 2% risk of failure between years five and 10, but those with under 500 had a 29% risk of failure. “Donor age should not be a factor in transplantation,” Dr. Holland said.



Richard Troutman, MD, presents the 2013 Troutman Award to Rafael Allan Oechsler, MD.

## Single-pass ultra-thin grafts and eye bank preparation

Using a single-pass technique to prepare donor tissue leaves a “slightly thicker periphery,” said **Erkin Abdullayev, MD**, Tampa, Fla., which may be beneficial in preserving endothelial cell density (ECD) during the life of the graft. A retrospective analysis of 199 consecutive grafts prepared by an eye bank with a standard microkeratome had an average ECD count of 3097 before the cut and a central corneal thickness (CCT) of 490 microns. Post-cut, the ECD was 3059 microns and the CCT was 81 microns. A total of 35 surgeons used the grafts (surgeons were in the U.S. and 12 other countries). There was one primary graft failure, five interface hazes, and three technical difficulties with insertion. “These grafts can be safely prepared in the eye bank with no increased risk of perforation and endothelial cell loss,” Dr. Abdullayev said.

## Steroid cessation linked to graft rejection

Overall rejection rates after DSAEK in patients with Fuchs’ endothelial dystrophy can be reduced with continued steroid use, said **Kevin Shah, MD**, Cincinnati. In his retrospective study on 400 patients with Fuchs’ and an average follow-up of 38 months, the overall rate of rejection was 4.3% (n=17), with most rejections occurring between months 24 and 36. “Our rejection rate was really low, which may be reflective of our patient population only including Fuchs,” he said. “But 50% of those rejections were in eyes that had completely stopped topical therapy.” Dr. Shah said that regardless of transplant technique, chronic steroid use is highly recommended. During the audience Q&A, it was also suggested (with anecdotal evidence) that graft patients increase their steroid use to four times daily one or two days before receiving a flu shot, and continue the higher dosage for 2–3 weeks after receiving their shot. Steroid choice is not as important as therapy maintenance, he said. **CN**



# Medical treatment of corneal diseases discussed at Cornea Subspecialty Day

**T**he first session of Cornea Subspecialty Day at the American Academy of Ophthalmology meeting focused on medical treatment of corneal diseases. **Bennie Jeng, MD**, Baltimore, discussed compounded therapies. His presentation looked at the history and current use of compounded therapies and whether they are worth the headache that they often cause. He said the history of compounded medication goes all the way back to the beginning of medicine, and they have continued to be used over time. Compounded medications can allow physicians the ability to use different doses and strengths of medications in different situations as they see fit, Dr. Jeng said. Several issues with these medications are the inconvenience for both the patient and the provider and the price. "It's expensive," Dr. Jeng said. "Many times insurance doesn't cover this." There is also the risk for contamination within compounding facilities, which can cause additional problems and headaches. Despite the potential for complications, Dr. Jeng said he believes that these medications are worth the hassle because they make it possible to use medications that are otherwise unavailable.

## Infections

In a session devoted entirely to infections, **Elisabeth Cohen, MD**, New York, discussed herpes zoster. She stressed the large percentage of people born in the U.S. age 40 and above who have had chicken pox whether they know it or not and are at risk for zoster. Dr. Cohen noted that the risk for herpes zoster will start to significantly increase at age 40 and will rise again sharply after age 50. Dr. Cohen said she does not believe it to be an epidemic because it occurs sporadically and is not highly conta-

gious. Additionally, there is a vaccine that can help reduce the overall burden of the disease. But there are also a number of barriers for the vaccine, including a high cost, reimbursement issues, and the production of it.

## Keratoprosthesis: Past, present, and future

**Claes Dohlman, MD**, Boston, gave a keynote lecture discussing keratoprosthesis. He discussed the progress that has been made with the Boston K-Pro

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## ASCRS·ASOA SYMPOSIUM & CONGRESS 2014 APRIL 25-29 BOSTON

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## Asia Cornea Society 2014 meeting update

**W**ith immense pleasure, we welcome all of you to join us in our upcoming 4th Asia Cornea Society Biennial Scientific Meeting to be held December 11–12, 2014 at the Taipei International Convention Center in Taipei, Taiwan.

Almost two years in planning, the Board of Council of the Asia Cornea Society and the Meeting Organizing Committee will be bringing you yet another stimulating scientific program that brings together an outstanding regional and international faculty of eminent speakers to discuss and deliberate on the current and emerging trends, latest research and clinical developments over the entire gamut of corneal

and external eye diseases. Delegates can look forward to a lively exchange of knowledge and information through a lineup of plenary lectures, themed symposia, case presentations, free papers, and scientific posters. As with our previous scientific meetings, you can look forward to a program filled with enlightening and vibrant discussions amid an atmosphere of fellowship and camaraderie allowing us to learn from each other with the ultimate goal of providing patients with better treatment and management. This intimate interaction has become a hallmark of our meeting where we reacquaint ourselves with old friends and colleagues and foster new ones in the process.

Be sure to spend time visiting the various wonderful attractions in Taipei where there is something exciting for everyone. The warmth and hospitality of the Taiwanese people is second to none, which we are sure will make your visit to Taipei a happy and memorable one.

We look forward to personally welcoming you to a great meeting held in exciting Taipei. **CN**

–**Professor Donald TH Tan**, President, Asia Cornea Society, and President, Association of Eye Banks of Asia

**Professor Fung-Rong Hu**, President, Organizing Committee, 4th Asia Cornea Society Scientific Meeting

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### Important Dates:

Abstract Submission Opens

On-line Registration Opens

Abstract Submission Closes

Notification of Abstract Review Results

Early-bird Registration Closes

Last Day for Cancellation of Registration with 75% Refund

On-line Registration Closes

December 2, 2013

December 2, 2013

September 01, 2014

September 25, 2014

October 15, 2014

October 15, 2014

November 12, 2014



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(also called the Dohlman-Doane, developed at Massachusetts Eye and Ear Infirmary, Boston) over the years. “To manage such a device with long-term safety has been extremely difficult,” he said. The past was terrible, with many issues and complications. In the present, there are some benefits of the device, and he said the future seems very promising. The primary complications have traditionally been tissue melt, infection, glaucoma, and inflammation, Dr. Dohlman said.

“Fortunately, the two first issues have been brought under reasonable control,” he said. But the two others still require work, particularly glaucoma.

### Crosslinking

The hot topic of corneal collagen crosslinking was discussed in a session.

**Roy Rubinfeld, MD**, Chevy Chase, Md., presented that not only is epi-on crosslinking safer than epi-off, but it is also highly effective. With the epi-off

procedure, there is a higher risk of haze, infections, and perforations, he said. Epi-on offers the advantage of being safer and being able to better treat thinner, steeper corneas, as well as pediatric corneas. He said that with the epi-on procedure, a patient is more like to return to regular vision and contact lens use in a short amount of time and there is relatively little time of discomfort. **CN**

## ASCRS Resident and Fellow Program

The ASCRS•ASOA Symposium & Congress provides innovative education and diverse networking opportunities. This half-day program focuses on critical aspects of business management for those beginning their careers in ophthalmology.

### Saturday, April 26

Sponsored by ASCRS Residents Task Force  
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ASOA Physician Relations Committee & Cornea Society

### Program Committee

Bonnie An Henderson, MD, Co-chair  
Edward J. Holland, MD, Co-chair  
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Thomas A. Oetting, MD  
Sherman W. Reeves, MD, MPH  
Tara A. Uhler, MD

- |      |  |
|------|--|
| 8:00 | <b>Welcome</b><br>Edward J. Holland, MD,<br>and Bonnie An Henderson, MD  |
| 8:05 | <b>Government Decisions Are Not Fait Accompli—<br/>How the Society and Physicians Can Shape the<br/>Future – Advice for the Young Physician</b><br>Nancey McCann |
| 8:15 | <b>How to Avoid Being Sued:<br/>What You Can Do to Reduce the<br/>Risk of Regulatory or Malpractice Liability</b>  |

- |       |   |
|-------|---|
| 8:30  | <b>Ethics – Good Habits to Start Making</b><br>John Banja, PhD  |
| 8:45  | <b>Coding and Billing 101</b><br>Kevin J. Corcoran, COE, CPC  |
| 9:00  | <b>Effective Communication Skills: Tips for Public<br/>Speaking, Writing and Publishing</b><br>Nick Mamalis, MD |
| 9:10  | <b>Demystifying the Path to the Podium</b><br>Jan E. Beiting  |
| 9:20  | <b>Break</b>  |
| 9:35  | <b>How to Choose a Fellowship</b><br>Sonia Yoo, MD  |
| 9:45  | <b>Nuts and Bolts of Finding a Job</b><br>Timothy Olsen, MD   |
| 10:00 | <b>How to Evaluate Employment Opportunities</b><br>Annette C. Sims, MD  |
| 10:15 | <b>Contract Negotiation</b><br>John B. Pinto  |
| 10:30 | <b>Why I Chose Academic Medicine</b><br>Maria E. Aaron, MD  |
| 10:40 | <b>Why I Chose Private Practice</b><br>Jeremy Z. Kieval, MD   |
| 10:50 | <b>Personal Finances 101</b><br>Sherman W. Reeves, MD, MPH  |
| 11:00 | <b>Networking and Referral Marketing</b><br>I. Howard Fine, MD  |
| 11:15 | <b>YPR Track Highlights</b><br>Sherman W. Reeves, MD, MPH   |
| 11:20 | <b>Best Paper and Poster Awards</b>   |
| 11:45 | <b>Lunch Roundtables with Faculty, ASCRS•ASOA<br/>and Cornea Society Committee Members</b>                      |

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## New developments for *Cornea*

### **Cornea makes impressive strides in 2013**

This year you may have noticed more articles being published in each issue of the journal *Cornea*. *Cornea* continues to receive increasing manuscript submissions each year, and publishing larger issues is one action that has helped

*Cornea* shorten its time to publication. For authors considering submitting a manuscript, the time from acceptance to publication in a print issue is now only four months. Additionally, thanks to great strides by the editorial office and editorial board, the time from submission to first decision has also



decreased. Authors may submit a paper online at [www.editorialmanager.com/cornea/](http://www.editorialmanager.com/cornea/) or visit the journal website at [www.corneajrnl.com](http://www.corneajrnl.com) to view the Instructions for Authors.

### **Take advantage of Cornea on the iPad**

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(Subject to Change)

- Recent Advances in Cataract Surgery for the Corneal Surgeon
- Refractive Surgery Success: Screening, Surgery and Beyond
- Surgical Pearls in Corneal Surgery: You NEED to SEE this
  - Current Management of External Ocular Infections: What Works, What Doesn't and What Might

### **Planning Committee**

Terry Kim, MD, Co-Chair  
Donald TH Tan, FRCS, Co-Chair

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Richard Davidson, MD  
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Christopher Starr, MD  
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### **Editor's article of the month**

The lead article in the December issue of *Cornea*, "Bimanual technique for insertion and positioning of endothelium-Descemet membrane graft in Descemet membrane endothelial keratoplasty," is by **Jose Guell, MD, PhD**, and his associates from Barcelona. They describe their DMEK technique, which uses 20% sulfur hexafluoride (SF6) to tamponade the graft. In their early experience, rebubbling was necessary in only 1 of 15 eyes. This method may increase the efficiency, safety, and acceptance of DMEK. **CN**

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**Congress President**  
**Prof. Vincenzo Sarnicola**

**KEY DATES**  
 Deadline abstract submission: 15 December 2013  
 Early bird registration fee: 31 January 2014

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## Inaugural Educational Summit wrap-up

In October the Cornea Society hosted the inaugural Cornea Fellows Educational Summit in Fort Worth, Texas—a two-day, intensive educational program that included both classroom and skills transfer lab components. It was designed to complement and reinforce cornea fellowship training.

Developed to address educational challenges identified by cornea fellowship directors, the 2013 Educational Summit set out to provide additional training to improve diagnostic and treatment skills within the clinic setting, instruction on patient selection and surgical techniques for refractive surgery, and technique pearls for routine and complex cataract surgery and corneal transplantation.

Through an integrated training program in both refractive and



**Shahzad Mian, MD, presents a talk during the Cornea Society Cornea Fellows Educational Summit in Fort Worth, Texas, in October.**

corneal transplant surgery, the 2013 Educational Summit enhances current fellowship training and prepares young ophthalmologists for their first years in practice. Led by course directors **Natalie Afshari, MD, W Barry Lee, MD, and Elmer Tu, MD**, the small faculty-to-student ratio provided hands-on training and an informal lecture setting. **Michael W. Belin, MD, Bennie H.**

**Jeng, MD, Terry Kim, MD, Shahzad Mian, MD, Christopher J. Rapuano, MD, and Charles D. Reilly, MD**, served on the Summit faculty.

The Society would like to thank the companies that provided educational grants to make this program possible: Alcon Laboratories at the Platinum Level and Moria Surgical at the Silver Level. **CN**



# 53rd Annual Meeting

**June 25-28, 2014**

The Hilton Portland  
and Executive Tower  
**Portland, OR**



2014 EBAA Scientific Symposium and Poster Session will be held June 28  
Call for Submissions will open in December 2013

[www.restoresight.org](http://www.restoresight.org)



# ILEVRO™

(nepafenac ophthalmic suspension) 0.3%

## BRIEF SUMMARY OF PRESCRIBING INFORMATION

### INDICATIONS AND USAGE

ILEVRO™ Suspension is indicated for the treatment of pain and inflammation associated with cataract surgery.

### DOSAGE AND ADMINISTRATION

#### Recommended Dosing

One drop of ILEVRO™ Suspension should be applied to the affected eye one-time-daily beginning 1 day prior to cataract surgery, continued on the day of surgery and through the first 2 weeks of the postoperative period. An additional drop should be administered 30 to 120 minutes prior to surgery.

#### Use with Other Topical Ophthalmic Medications

ILEVRO™ Suspension may be administered in conjunction with other topical ophthalmic medications such as beta-blockers, carbonic anhydrase inhibitors, alpha-agonists, cycloplegics, and mydriatics. If more than one topical ophthalmic medication is being used, the medicines must be administered at least 5 minutes apart.

### CONTRAINDICATIONS

ILEVRO™ Suspension is contraindicated in patients with previously demonstrated hypersensitivity to any of the ingredients in the formula or to other NSAIDs.

### WARNINGS AND PRECAUTIONS

#### Increased Bleeding Time

With some nonsteroidal anti-inflammatory drugs including ILEVRO™ Suspension, there exists the potential for increased bleeding time due to interference with thrombocyte aggregation. There have been reports that ocularly applied nonsteroidal anti-inflammatory drugs may cause increased bleeding of ocular tissues (including hyphemas) in conjunction with ocular surgery. It is recommended that ILEVRO™ Suspension be used with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.

#### Delayed Healing

Topical nonsteroidal anti-inflammatory drugs (NSAIDs) including ILEVRO™ Suspension, may slow or delay healing. Topical corticosteroids are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.

#### Corneal Effects

Use of topical NSAIDs may result in keratitis. In some susceptible patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs including ILEVRO™ Suspension and should be closely monitored for corneal health. Postmarketing experience with topical NSAIDs suggests that patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases (e.g., dry eye syndrome), rheumatoid arthritis, or repeat ocular surgeries within a short period of time may be at increased risk for corneal adverse events which may become sight threatening. Topical NSAIDs should be used with caution in these patients.

Postmarketing experience with topical NSAIDs also suggests that use more than 1 day prior to surgery or use beyond 14 days post surgery may increase patient risk and severity of corneal adverse events.

#### Contact Lens Wear

ILEVRO™ Suspension should not be administered while using contact lenses.

### ADVERSE REACTIONS

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to the rates in the clinical studies of another drug and may not reflect the rates observed in practice.

#### Ocular Adverse Reactions

The most frequently reported ocular adverse reactions following cataract surgery were capsular opacity, decreased visual acuity, foreign body sensation, increased intraocular pressure, and sticky sensation. These events occurred in approximately 5 to 10% of patients.

Other ocular adverse reactions occurring at an incidence of approximately 1 to 5% included conjunctival edema, corneal edema, dry eye, lid margin crusting, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, photophobia, tearing and vitreous detachment.

Some of these events may be the consequence of the cataract surgical procedure.

### Non-Ocular Adverse Reactions

Non-ocular adverse reactions reported at an incidence of 1 to 4% included headache, hypertension, nausea/vomiting, and sinusitis.

### USE IN SPECIFIC POPULATIONS

#### Pregnancy

##### Teratogenic Effects.

**Pregnancy Category C:** Reproduction studies performed with nepafenac in rabbits and rats at oral doses up to 10 mg/kg/day have revealed no evidence of teratogenicity due to nepafenac, despite the induction of maternal toxicity. At this dose, the animal plasma exposure to nepafenac and amfenac was approximately 70 and 630 times human plasma exposure at the recommended human topical ophthalmic dose for rats and 20 and 180 times human plasma exposure for rabbits, respectively. In rats, maternally toxic doses  $\geq 10$  mg/kg were associated with dystocia, increased post-implantation loss, reduced fetal weights and growth, and reduced fetal survival.

Nepafenac has been shown to cross the placental barrier in rats. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, ILEVRO™ Suspension should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

#### Non-teratogenic Effects.

Because of the known effects of prostaglandin biosynthesis inhibiting drugs on the fetal cardiovascular system (closure of the ductus arteriosus), the use of ILEVRO™ Suspension during late pregnancy should be avoided.

#### Nursing Mothers

ILEVRO™ Suspension is excreted in the milk of lactating rats. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ILEVRO™ Suspension is administered to a nursing woman.

#### Pediatric Use

The safety and effectiveness of ILEVRO™ Suspension in pediatric patients below the age of 10 years have not been established.

#### Geriatric Use

No overall differences in safety and effectiveness have been observed between elderly and younger patients.

### NONCLINICAL TOXICOLOGY

#### Carcinogenesis, Mutagenesis, Impairment of Fertility

Nepafenac has not been evaluated in long-term carcinogenicity studies. Increased chromosomal aberrations were observed in Chinese hamster ovary cells exposed *in vitro* to nepafenac suspension. Nepafenac was not mutagenic in the Ames assay or in the mouse lymphoma forward mutation assay. Oral doses up to 5,000 mg/kg did not result in an increase in the formation of micronucleated polychromatic erythrocytes *in vivo* in the mouse micronucleus assay in the bone marrow of mice. Nepafenac did not impair fertility when administered orally to male and female rats at 3 mg/kg.

### PATIENT COUNSELING INFORMATION

#### Slow or Delayed Healing

Patients should be informed of the possibility that slow or delayed healing may occur while using nonsteroidal anti-inflammatory drugs (NSAIDs).

#### Avoiding Contamination of the Product

Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye or surrounding structures because this could cause the tip to become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

Use of the same bottle for both eyes is not recommended with topical eye drops that are used in association with surgery.

#### Contact Lens Wear

ILEVRO™ Suspension should not be administered while wearing contact lenses.

#### Intercurrent Ocular Conditions

Patients should be advised that if they develop an intercurrent ocular condition (e.g., trauma, or infection) or have ocular surgery, they should immediately seek their physician's advice concerning the continued use of the multi-dose container.

#### Concomitant Topical Ocular Therapy

If more than one topical ophthalmic medication is being used, the medicines must be administered at least 5 minutes apart.

#### Shake Well Before Use

Patients should be instructed to shake well before each use. U.S. Patent Nos. 5,475,034; 6,403,609; and 7,169,767.

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Fort Worth, Texas 76134 USA  
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# ILEVRO™ Suspension

Designed to put potency  
precisely where you need it<sup>1,2</sup>

## ONCE-DAILY POST-OP

One drop should be applied once daily beginning 1 day prior to surgery through 14 days post-surgery, with an additional drop administered 30 to 120 minutes prior to surgery<sup>3</sup>

Use of ILEVRO™ Suspension more than 1 day prior to surgery or use beyond 14 days post-surgery may increase patient risk and severity of corneal adverse events<sup>3</sup>

### INDICATIONS AND USAGE

ILEVRO™ Suspension is a nonsteroidal, anti-inflammatory prodrug indicated for the treatment of pain and inflammation associated with cataract surgery.

#### Dosage and Administration

One drop of ILEVRO™ Suspension should be applied to the affected eye one-time-daily beginning 1 day prior to cataract surgery, continued on the day of surgery and through the first 2 weeks of the postoperative period. An additional drop should be administered 30 to 120 minutes prior to surgery.

### IMPORTANT SAFETY INFORMATION

#### Contraindications

ILEVRO™ Suspension is contraindicated in patients with previously demonstrated hypersensitivity to any of the ingredients in the formula or to other NSAIDs.

#### Warnings and Precautions

- **Increased Bleeding Time** – With some nonsteroidal anti-inflammatory drugs including ILEVRO™ Suspension there exists the potential for increased bleeding time. Ocularly applied nonsteroidal anti-inflammatory drugs may cause increased bleeding of ocular tissues (including hyphema) in conjunction with ocular surgery.
- **Delayed Healing** – Topical nonsteroidal anti-inflammatory drugs (NSAIDs) including ILEVRO™ Suspension may slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.
- **Corneal Effects** – Use of topical NSAIDs may result in keratitis. In some patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use.

Patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases (e.g., dry eye syndrome), rheumatoid arthritis, or repeat ocular surgeries within a short period of time may be at increased risk for corneal adverse events which may become sight threatening. Topical NSAIDs should be used with caution in these patients.

Use more than 1 day prior to surgery or use beyond 14 days post-surgery may increase patient risk and severity of corneal adverse events.

- **Contact Lens Wear** – ILEVRO™ Suspension should not be administered while using contact lenses.

#### Adverse Reactions

The most frequently reported ocular adverse reactions following cataract surgery occurring in approximately 5 to 10% of patients were capsular opacity, decreased visual acuity, foreign body sensation, increased intraocular pressure, and sticky sensation.

**For additional information about ILEVRO™ Suspension, please refer to the brief summary of prescribing information on adjacent page.**

**References:** 1. Ke T-L, Graff G, Spellman JM, Yanni JM. Nepafenac, a unique nonsteroidal prodrug with potential utility in the treatment of trauma-induced ocular inflammation, II: In vitro bioactivation and permeation of external ocular barriers. *Inflammation*. 2000;24(4):371-384. 2. Data on file. 3. ILEVRO™ Suspension package insert.

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